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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,484	07/09/2001	Daniel Cohen	GEN-T111XC3D2	6608
23557	7590	01/04/2006	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			FREDMAN, JEFFREY NORMAN	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/901,484

Applicant(s)

COHEN ET AL.

Examiner

Jeffrey Fredman

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 50-53, 56-58, 60, 63, 64, 67, 68 and 71-86 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 50-53, 56-58, 63, 64, 67, 68, 71, 72 and 74-84 is/are rejected.
- 7) ☒ Claim(s) 60, 73, 85 and 86 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 29, 2005 has been entered.

### ***Priority***

2. The current application claims priority to a series of cases dating back to 1997. However, the claims are not given priority to applications 08/996,306 and 60/099,658 because in the current application SEQ ID NO: 179 is 56,520 nucleotides while in those parent applications, the largest sequences were 56,516 nucleotides. Consequently, there is no possibility that these applications provide full descriptive support for SEQ ID NO: 179, and priority to these applications is denied. Therefore, for purposes of prior art, the priority date of this application is limited to 09/218,207, filed December 22, 1998, which provides the full 56,520 nucleotides of SEQ ID NO: 179.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 50-52, 56-58, 63, 64, 67, 68, 71-72 and 74-84 are rejected under 35

U.S.C. 102(a) and (b) as being anticipated by Osoegawa et al (Genomics (1998)52:1-8)

as evidenced by Genbank Accession No. AC009631 and an email from Pieter de Jong (attached).

Osoegawa teaches synthesis of BAC chromosome libraries (abstract). In particular, Osoegawa teaches the synthesis of a particular BAC library termed RPCI-11 (also called RP11) which was grown in bacterial host cells using recombinant vectors which were placed onto filters and the nucleic acid was isolated (page 2 and page 3, column 1).

A specific isolated BAC, RP11-372K15 which is in a composition of this library and which is at a specific location on the arrays sold by the BACPAC consortium, comprises 606 contiguous nucleotides from nucleotides that overlap position 54516-55209 of SEQ ID NO: 179. The BAC also comprises 1100 nucleotides from 53260 to 54360 of SEQ ID NO: 179 which encompasses positions 53272, 53389, 53511, 53600, 53665 and 53815. Further, the BAC also comprises a 180 nucleotide region which encompasses position 54365. As shown by the alignment below, this BAC has close match with the reference sequence.

SEQ: 179	53260	TTAGCCAGGCATGGTGGCGTACACTGAGTAGTTTGTCCCAGCTACTCGGGAGGGTGAGGT
53319		
AC009631	2473	TTAGCCAGGCATGGTGGCGTACACTGAGTAGTTTGTCCCAGCTACTCGGGAGGGTGAGGT
2532		
SEQ: 179	53320	GGGAGGATCGCTTCAGCCCAGGAGGTTGAGATTGCAGTGAGCCATGGACATACCACTGCA
53379		

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AC009631 2533 GGGAGGATCGCTTCAGCCCAGGAGGTTGAGATTGCAGTGAGCCATGGACATACCACTGCA  
2592

SEQ: 179 53380 CTACAGCCTAGGTAACAGCACGAGACCCCAACTCTTAGAAAAATGAAAAGGAAATATAGAA  
53439

AC009631 2593 CTACAGCCTAGGTAACAGCACGAGACCCCAACTCTTAGAAAAATGAAAAGGAAATATAGAA  
2652

SEQ: 179 53440 ATATAAAATTTGCTTATTATAGACACACAGTAACTCCCAGATATGTACCACAAAAAATGT  
53499

AC009631 2653 ATATAAAATTTGCTTATTATAGACACACAGTAACTCCCAGATATGTACCACAAAAAATGT  
2712

SEQ: 179 53500 GAAAAGAGAGAGAAATGTCTACCAAAGCAGTATTTTGTGTGTATAATTGCAAGCGCATAG  
53559

AC009631 2713 GAAAAGAGAGAGAAATGTCTACCAAAGCAGTATTTTGTGTGTATAATTGCAAGCGCATAG  
2772

SEQ: 179 53560 TAAAAATAATTTTAACCTTAATTTGTTTTTAGTAGTGTTTAGATTGAAGATTGAGTGAAAT  
53619

AC009631 2773 TAAAAATAATTTTAACCTTAATTTGTTTTTAGTAGTGTTTAGATTGAAGATTGAGTGAAAT  
2832

SEQ: 179 53620 ATTTTCTTGGCAGATATTCCGTATCTGGTGGAAAGCTACAATGCAATGTCGTTGTAGTTT  
53679

AC009631 2833 ATTTTCTTGGCAGATATTCCGTATCTGGTGGAAAGCTACAATGCAATGTCGTTGTAGTTT  
2892

SEQ: 179 53680 TGCATGGCTTGCTTTATAAACAAGATTTTTTCTCCCTCCTTTTGGGCCAGTTTTTCATTAC  
53739

AC009631 2893 TGCATGGCTTGCTTTATAAACAAGATTTTTTCTCCCTCCTTTTGGGCCAGTTTTTCATTAC  
2952

SEQ: 179 53740 GAGTAACTCACACTTTTTTGATTAAAGAACTTGAAATTACGTTATCACTTAGTATAAATTGA  
53799

AC009631 2953 GAGTAACTCACACTTTTTTGATTAAAGAACTTGAAATTACGTTATCACTTAGTATAAATTGA  
3012

SEQ: 179 53800 CATTATATAGAGACTATGTAACATGCAATCATTAGAATCAAAATTAGTACTTTGGTCAAA  
53859

AC009631 3013 CATTATATAGAGACTATGTAACATGCAATCATTAGAATCAAAATTAGTACTTTGGTCAAA  
3072

SEQ: 179 53860 ATATTTACAACATTACATACTTGTCAAATATTCATGTAATTAAGTGAATTTAAACCTT  
53919

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AC009631 3073 ATATTTTACAACATTTCACATACTTGTCAAATATTCATGTAATTAACTGAATTTAAAACCTT  
3132

SEQ: 179 53920 CAACTATTATGAAGTGCTCGTCTGTACAATCGCTAATTTACTCAGTTTAGAGTAGCTACA  
53979

AC009631 3133 CAACTATTATGAAGTGCTCGTCTGTACAATCGCTAATTTACTCAGTTTAGAGTAGCTACA  
3192

SEQ: 179 53980 ACTCTTCGATACTATCATCAATATTTGACATCTTTTCCAATTTGTGTATGAAAAGTAAAT  
54039

AC009631 3193 ACTCTTCGATACTATCATCAATATTTGACATCTTTTCCAATTTGTGTATGAAAAGTAAAT  
3252

SEQ: 179 54040 CTATTCCGTAGCAACTGGGGAGTCATATATGAGGTCAAAGACATATACCTTGTTATTAT  
54099

AC009631 3253 CTATTCCGTAGCAACTGGGGAGTCATATATGAGGTCAAAGACATATACCTTGTTATTAT  
3312

SEQ: 179 54100 AATATGTATACTATAATAATAGCTGGTTATCCTGAGCAGGGGAAAAGGTTATTTTTAGGA  
54159

AC009631 3313 AATATGTATACTATAATAATAGCTGGTTATCCTGAGCAGGGGAAAAGGTTATTTTTAGGA  
3372

SEQ: 179 54160 AAACCACTTCAAATAGAAAGCTGAAGTACTTCTAATATACTGAGGGAAGTATAATATGTG  
54219

AC009631 3373 AAACCACTTCAAATAGAAAGCTGAAGTACTTCTAATATACTGAGGGAAGTATAATATGTG  
3432

SEQ: 179 54220 GAACAAACTCTCAACAAAATGTTTATTGATGTTGATGAAACAGATCAGTTTTTCCATCCG  
54279

AC009631 3433 GAACAAACTCTCAACAAAATGTTTATTGATGTTGATGAAACAGATCAGTTTTTCCATCCG  
3492

SEQ: 179 54280 GATTATTATTGGTTCATGATTTTATATGTGAATATGTAAGATATGTTCTGCAATTTTATA  
54339

AC009631 3493 GATTATTATTGGTTCATGATTTTATATGTGAATATGTAAGATATGTTCTGCAATTTTATA  
3552

SEQ: 179 54340 AATGTTTCATGTC - nnnnnnnnAAAAAAGGTGCTATTGAAATTCTGTGTCCTCAGCAGGCAA  
54398

AC009631 3553 AATGTTTCATGTCCTTTTTTTTAAAAAAGGTGCTATTGAAATTCTGTGTCCTCAGCAGGCAA  
3612

SEQ: 179 54399 GAATACTTGACTAACTCTTTTTGTCTCTTTATGGTATTTTCAGAATAAAGTCTGACTTGT  
54458

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AC009631 3613 GAATACTTGACTAACTCTTTTTGTCTCTTTATGGTATTTTCAGAATAAAGTCTGACTTGT  
3672

SEQ: 179 54459 GTTTTTGAGATTATTGGTGCCCTCATTAATTCAGCAATAAAGGAAAATATGCATCTCAAAA  
54518

AC009631 3673 GTTTTTGAGATTATTGGTGCCCTCATTAATTCAGCAATAAAGGAAAATATGCATCTCAAAA  
3732

SEQ: 179 54519 ATTGGTGATAAAAAGTTATTTCTGTATATGTGATAAAGTTTACATGTTGTGTATATATG  
54578

AC009631 3733 ATTGGTGATAAAAAGTTATTTTCATGTATATGTGATAAAGTTTACATGTTGTGTATATATG  
3792

SEQ: 179 54579 TTGTATTGCCAAATACGGCTATTAAATACTACGTCATATTTTAAAGGTTTCAGTTTGTAGT  
54638

AC009631 3793 TTGTATTGCCAAATACGGCTATTAAATACTACGTCATATTTTAAAGGTTTCAGTTTGTAGT  
3852

SEQ: 179 54639 GATAGTAAACAAGCAGTGCACCTAAGCCTCTTGCGGGCATCATCTCATCTCACTGTCATCA  
54698

AC009631 3853 GATAGTAAACAAGCAGTGCACCTAAGCCTCTTGCGGGCATCATCTCATCTCACTGTCATCA  
3912

SEQ: 179 54699 CAAACCCCATGCCACAGCGTAGCTTGACCACTAAAAGTAATGCATCTGCAAGCATACTGC  
54758

AC009631 3913 CAAACCCCATGCCACAGCGTAGCTTGACCACTAAAAGTAATGCATCTGCAAGCATACTGC  
3972

SEQ: 179 54759 CAGGTTTTGGTAGTTTGTACCAACAGTTACCTTATCAAGGTAAATCCCAGACTCTAAAA  
54818

AC009631 3973 CAGGTTTTGGTAGTTTGTACCAACAGTTACCTTATCAAGGTAAATCCCAGACTCTAAAA  
4032

SEQ: 179 54819 GAGTTGGTGCTGTGTCACTACATGCATAACTTTAAATAAATTTCTGCGGGCGCGGTGG  
54878

AC009631 4033 GAGTTGGTGCTGTGTCACTACATGCATAACTTTAAATAAATTTCTGCGGGCGCGGTGG  
4092

SEQ: 179 54879 CTCACGCCTGTAATCCCAGCAGTTTGGGAGGCCGAGGCAAGTGGATCACTTGAGGTCAGG  
54938

AC009631 4093 CTCACGCCTGTAATCCCAGCAGTTTGGGAGGCCGAGGCAAGTGGATCACTTGAGGTCAGG  
4152

SEQ: 179 54939 AGTTTGAGACCAGCCTGGCCAACGTGGTGAAACCCTGTCTCTACTAAAAATACAAAAATT  
54998

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AC009631  4153  AGTTTGAGACCAGCCTGGCCAACGTGGTGAAACCCTGTCTCTACTAAAAATACAAAAATT
4212

SEQ: 179   54999 AGCCAGGCGTGTGGTGGCAGGCACCTGTAATCCCAGCTACTTGGGAGGATGAGGCAGGAG
55058

AC009631  4213  AGCCAGGCGTGTGGTGGCAGGCACCTGTAATCCCAGCTACTTGGGAGGATGAGGCAGGAG
4272

SEQ: 179   55059 AATCATTTGAATCCTGCAGGCGGAGGTTGCAGTGAGCCAAGATGGCGTCATTGCACTCCA
55118

AC009631  4273  AATCATTTGAATCCTGCAGGCGGAGGTTGCAGTGAGCCAAGATGGCGTCATTGCACTCCA
4332

SEQ: 179   55119 GCCTGGGCGACAAGAGCGAGACTCCGTATT  55148
AC009631  4333  GCCTGGGCGACAAGAGCGAGACTCCGTATT  4362

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The above alignment, meets several of the elements of claim 50. The sequence meets element (a) because there are more than 1000 consecutive nucleotides of SEQ ID NO: 179, specifically nucleotides 53260 to 54360 which comprise 1100 consecutive nucleotides of SEQ ID NO: 179. This sequence also comprises the complement claimed in (d) and meets (e) for all of positions 53272, 53389, 53511, 53600, 53665, 53815 and 54365 of SEQ ID NO: 179, where N is one of these listed positions and X is within the range of 8-30, including 8, 10, 12, 15, 20 or 25.

The email of Pieter de Jong indicates that filters from the RPCI-11 library were first publicly available, used and sold on August 1, 1997.

With regard to claim 51, Osoegawa teaches that the sequences were in Bac vectors (see page 1, column 2, subheading "BAC/PAC vector preparation").

With regard to claim 52, Osoegawa teaches that the vectors were in bacterial host cells (see page 2, column 1).



With regard to claim 56, Osoegawa teaches that the sequences were in vectors, and the vector sequence can function as a label for the detection of the target sequence (see page 1, column 2. To explain, a DNA sequence may itself be a label, and frequently is used as such, since specific DNA can be detected by hybridization).

With regard to claims 57-58, Osoegawa teaches that the oligonucleotide is attached, indirectly, to a solid support (see page 2, column 1 and email, where filters were sold).

With regard to claims 63-64, Osoegawa teaches a library which would comprise the RPCI-11 library, which Genbank Accession No. AC009631 shows has 1100 contiguous nucleotides in the claimed region (see alignment above).

With regard to claims 67-68, Osoegawa also anticipates these claims for the reasons discussed above.

With regard to claims 71-72, 74-84 , Osoegawa teaches oligonucleotides of 1100 contiguous nucleotides which comprise a contiguous span of more than 1000 nucleotides overlapping positions 53260 to 54360 (see alignment above).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osoegawa et al (Genomics (1998)52:1-8) in view of Capecchi et al (Science (1989) 244:1288-1292).

Osoegawa teaches vectors that comprise sequences of interest as discussed above.

Capecchi teaches the use of homologous recombination to form host cells and mammals (see page 1280, figure 1, for example).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to screen each of the sequences of Osoegawa for functional activity using the homologous recombination method of Capecchi since Capecchi states "Targeted disruption of these genes may not only reveal the phenotypes associated with inactivation of the individual genes, but through epistasis and molecular analyses, may also help define the developmental network controlling early mouse morphogenesis (see page 1292, column 1)." Thus, an ordinary

practitioner, interested in identifying what phenotype is associated with the sequence of the sequences of Osoegawa would have been motivated by Capecchi to use targeted disruption in order to define the phenotype of the genes with which the sequence of Osoegawa are associated.

***Allowable Subject Matter***

8. Claims 60 and 73 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Claims 85 and 86 are allowed.

10. The following is a statement of reasons for the indication of allowable subject matter: Claims 85 and 86 are drawn to specific primers and probes which "consist" of probes or primers that overlap one of the 67 different positions listed as N. An oligomer search of the sequence did not find any oligomers which met the conditions of the claim. Claim 60 is drawn to the complete SEQ ID NO: 179. No such sequence was found in the sequence search and while the evidence from the chromosome 8 hits is that there is generally 99.8% or so alignment with hundreds of contiguous basepairs, there is no evidence that Weier is inherently identical over the entire length of SEQ ID NO: 179. Therefore, the claim to the entire sequence is novel and unobvious. With regard to claim 73, no sequences with at least 40 contiguous bases of SEQ ID NO: 179 at the specified positions were found in the sequence search. Therefore, these fragments are novel and unobvious.

***Response to Arguments***

11. Applicant's arguments filed November 29, 2005 have been fully considered but they are not persuasive.

Applicant amended the claims by deleting certain members of the Markush group of positions. A further search determined that some of the later positions are also found in the same Genbank accession number previously cited and therefore the indicated claims are anticipated or rendered prima facie obvious for the reasons given above.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**JEFFREY FREDMAN**  
**PRIMARY EXAMINER**

11/29/05